

Department of Health and Human Services
National Human Research Protections Advisory Committee (NHRPAC) Meeting
Monday, April 9 & Tuesday, April 10, 2001

Pooks Hill Marriott
5151 Pooks Hill Road
Bethesda, Maryland
301/897-9400

AGENDA

Monday April 9, 2001

8:30am – 9:15am	Welcome:	[45 minutes]
	Introduction of New Members	[5 minutes each]
	(brief comments about yourself; areas of particular concern)	
	<i>Mary Faith Marshall, Ph.D.</i>	
	<i>Chairperson NHRPAC</i>	
	Office for Human Research Protection	[10 minutes]
	Updates	
	<i>Greg Koski, Ph.D., M.D., Director, OHRP,</i>	
	<i>Executive Secretary, NHRPAC</i>	
	<i>Chairman, HSRS</i>	
	Clarification of NHRPAC Roles	
	<i>Mary Faith Marshall, Ph.D.</i>	[10 minutes]
9:15am – 9:30am	The Department's Commitment to	[15 minutes]
	Protection of Human Subjects	
	<i>The Honorable David Satcher, M.D., Ph.D.,</i>	
	<i>Surgeon General</i>	
9:30am – 11:00am	Update: Financial Relationships	[1 hour, 30 minutes]
	<i>Mark Barnes, J.D.</i>	[40 minutes]
	PRESENTATION LINK: [Powerpoint] [PDF]	
	<i>Chair, Working Group</i>	
	Committee Discussion	[50 minutes]
[10:30am – 10:45am]	BREAK	[15 minutes]

11:00am – 11:45am	Update: Declaration of Helsinki <i>Greg Koski, Ph.D., M.D.</i>	[45 minutes]
11:45am – 12:15pm	Public Comment	[30 minutes]
12:15pm – 1:30pm	LUNCH - On your own	
1:30pm – 4:30pm	Genetics Genetic Research: An overview	
1:30pm – 2:15pm	<i>Francis Collins, M.D., Ph.D.</i> PRESENTATION LINK: [Powerpoint] [PDF] <i>Director, National Human Genome Research Institute</i>	[45 minutes]
2:15pm – 4:30pm	Panel Discussion <i>Moderator Francis Collins, M.D., Ph.D.</i> Family Members/Third Parties: Should Family Members/Third Parties of Survey Subjects, Themselves become Subjects of a Protocol— if so, Must Informed Consent be Obtained for Investigator to Retain Private Information on these Individuals?	
2:15pm – 3:15pm	Guest Panel: <i>Jeff Botkin, M.D., M.P.H.</i> PRESENTATION LINK: [Powerpoint] [PDF] <i>Department of Pediatrics The University of Utah Medical Center</i> <i>Terri Arledge, Ph.D.</i> PRESENTATION LINK: [Powerpoint] [PDF] <i>GalaxoSmithKline</i> <i>Sharon Terry</i> <i>Vice President for Consumers Genetic Alliance and President of PXE International</i> <i>Terri Seargent</i> <i>Consumer Advocate Alpha1 Association</i>	[1 hour] [15 minutes] [15 minutes] [15 minutes] [15 minutes]
[3:15pm – 3:30pm]	BREAK	[15 minutes]

3:30pm – 4:30pm	Discussion	[1 hour]
4:30pm – 5:15pm	Public Comment	[45 minutes]
5:15pm – 5:30pm	Closing Comments/ADJOURN	[15 minutes]

Tuesday, April 10, 2001

8:30am – 8:45am	Brief Recap of Day One Questions/Clarifications <i>Mary Faith Marshall, Ph.D.</i>	[15 minutes]
8:45am – 9:00am	The National Institutes of Health and Human Subject Protections <i>Ruth Kirschstein, M.D.</i> <i>Acting Director, National Institutes of Health</i>	[15 minutes]
9:00am – 12:00pm	Children	[3 hours]
9:00am – 9:45am	Discussion of Current Definitions and their Interpretation <i>NHRPAC Committee</i>	[45 minutes]
9:45am – 10:15am	Update: Children's Workgroup <i>Alan Fleischman, M.D.</i> <i>Senior Vice President, NY Academy of Medicine</i> <i>Clinical Professor of Pediatrics and Clinical Professor</i> <i>of Epidemiology & Social Medicine, Albert Einstein</i> <i>College, New York</i>	[30 minutes]
[10:15am – 10:30am]	BREAK	[15 minutes]
10:30am – 11:45am	Committee Discussion	[1 hour, 15 minutes]
11:45am – 12:00pm	The National Science Foundation and Human Subject Protections <i>Rita Colwell, Ph.D.</i> <i>Director, National Science Foundation</i>	[15 minutes]
12:00pm – 1:30pm	LUNCH – on your own	[1 hour, 30 minutes]

1:30pm – 2:15pm	Update: Social Science and Discussion <i>Felice Levine, Ph.D.</i> <i>Executive Officer</i> <i>American Sociological Association;</i> <i>Philip Rubin, Ph.D.</i> <i>Director, Division of Behavioral and Cognitive Sciences</i> <i>National Science Foundation</i>	[45 minutes]
2:15pm – 3:15pm	Public Comment	[1 hour]
[3:15pm – 3:30pm]	BREAK	[15 minutes]
3:30pm – 4:15pm	Meeting Recap Review Recommendations: Financial Relationships Declaration of Helsinki Genetics Family Members/Subjects Children Social Science <i>Mary Faith Marshall, Ph.D.</i>	[45 minutes]
4:15pm	THANK YOU – ADJOURN	